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No. 92-

IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Petitioner,

v.

KATHLEEN E. LES; FRANCES LES THOMAS; MANUEL JESUS PEREZ MORALES; DAVID R. PEREZ; MANUEL R. PEREZ,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Does the United States Environmental Protection Agency have authority to establish a "*de minimis*" exception to § 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the food additive "Delaney clause") to allow use of agricultural pesticides which are carcinogenic in laboratory animals, but pose virtually no risk of cancer to consumers of processed foods?

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Ninth Circuit is reported as *Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992), and is reproduced in the Appendices to this Petition as Appendix ("App.") A at 1a. The Final Order of the United States Environmental Protection Agency ("EPA") reviewed by the court of appeals was published at 56 Fed. Reg.

7750 (Feb. 25, 1991), and is reproduced as App. B at 12a.[1]

JURISDICTION

The judgment of the court of appeals was entered on July 8, 1992. A petition for rehearing was filed by EPA and denied on September 25, 1992. This Court has jurisdiction under 28 U.S.C. § 1254(1) (1988).

STATUTORY PROVISIONS INVOLVED

The two federal statutes involved in this case are the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C.A. §§ 301-394 (West 1972 & Supp. 1992), and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y (1988 & Supp. III 1991). The pertinent portions of these statutes are reproduced in App. C at 115a (FFDCA) and 121a (FIFRA).

STATEMENT OF THE CASE

Technological advances now make it possible to calculate human health risks more insignificant than ever before identifiable. Does EPA have authority, despite the antiquated language of FFDCA's food additive

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[1] Petitioner National Agricultural Chemicals Association ("NACA"), which has no corporate parent or subsidiaries, is a national, nonprofit trade association whose members manufacture, formulate and distribute virtually all of the agricultural pesticides used in the United States. NACA intervened below in support of EPA and its Administrator, William K. Reilly, the respondents below. The AFL-CIO, Natural Resources Defense Council, and Public Citizen were petitioner-intervenors below.

"Delaney clause," 21 U.S.C. § 348(c)(3)(A) (1988), to take these scientific advances into account by allowing the use of agricultural pesticides which have been found to induce cancer in laboratory animals, but whose residues in processed foods pose no more than a trivial (i.e., practically nonexistent) dietary risk of cancer to consumers? The American public, agriculture, the food and pesticide industries, and EPA's pesticide regulatory program, are directly affected by this nationally significant issue.

A. The Statutory Scheme for Pesticides

The food additive Delaney clause is a small and anomalous part of the pesticide regulatory scheme. Pesticides are regulated primarily under FIFRA, which this Court has accurately described as "a comprehensive regulatory statute." *Wisconsin Public Intervenor v. Mortier*, 111 S. Ct. 2476, 2480 (1991) (quoting *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984)). Before a pesticide can be sold or distributed, it must be granted a registration by EPA pursuant to FIFRA. *See* 7 U.S.C. § 136a. "A pesticide may be registered only if it does not cause 'unreasonable adverse effects' on human health or the environment, a standard that is applied by weighing the benefits of a pesticide against its risks." *Nader v. EPA*, 859 F.2d 747, 748 (9th Cir. 1988), *cert. denied*, 490 U.S. 1034 (1989).[2] To implement this FIFRA risk-benefit standard, "EPA is required . . . to consider

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[2] FIFRA provides, *inter alia*, that "[t]he Administrator shall register a pesticide if the Administrator determines that . . . (C) it will perform its intended function without unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). "The term 'unreasonable adverse effects on the environment' means

the *degree of risk* posed by the pesticide and the benefits it provides" before determining whether it can be registered for use. App. B at 19a (emphasis added). Pesticide manufacturers must fulfill EPA's elaborate requirements for submission of numerous types of state-of-the-art scientific studies, including carcinogenicity feeding studies conducted on laboratory animals, so that EPA can make the risk-benefit determination mandated by FIFRA for each agricultural pesticide. *See* 40 C.F.R. pt. 158 (1992).[3]

EPA evaluates the safety and use of every agricultural pesticide under FIFRA's risk-benefit standard. Indeed, when Congress enacted the modern FIFRA in 1972, it recognized that "[w]hile appropriate pesticides properly used are essential to man . . . . [s]ome may be taken up in the food chain," and thus "[t]heir wise control *based on a careful balancing of benefit versus risk* to determine what is best for man is essential." S. Rep. No. 838, 92d Cong., 2d Sess. 4, *reprinted in* 1972 U.S.C.C.A.N. 3993, 3996 (emphasis added).

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any unreasonable risk to man or the environment, taking into account the economic, social, and environmental *costs and benefits* of the use of any pesticide." 7 U.S.C. § 136(bb) (emphasis added).

[3] FIFRA's risk-benefit standard also governs interim administrative review, cancellation, and suspension of previously registered pesticides. *See* 7 U.S.C. §§ 136a(c)(3)(8), 136d(b), 136d(c). In addition, the risk-benefit standard governs reregistration, a procedure which requires manufacturers to submit updated health and safety data so that EPA can determine whether a previously registered pesticide continues to meet the risk-benefit standard. *See* 7 U.S.C. § 136a-1.

FFDCA plays a subordinate role in the overall pesticide regulatory scheme. It fulfills an enforcement function by requiring EPA to establish tolerances (i.e., maximum allowable concentrations in crops and processed foods) for residues of agricultural pesticides whose safety is evaluated, and registration and use regulated, pursuant to FIFRA's risk-benefit standard.[4] Under FFDCA § 408 ("Tolerances for pesticide chemicals in or on raw agricultural commodities"), 21 U.S.C. § 346a, a food crop is deemed to be "adulterated," and hence subject to seizure, unless EPA has established a tolerance, or granted an exemption, for pesticide residues in or on the crop.[5] In setting a § 408 tolerance "to the extent necessary to protect the public health," EPA is required to "give appropriate consideration, among other relevant factors . . . to the necessity for the production of an adequate, wholesome, and economical food supply." 21 U.S.C. § 346a(b). Thus, § 408 "expressly gives [EPA] the authority to balance risks against benefits in determining appropriate tolerance levels" for pesticide residues in crops. 53 Fed. Reg. 41,104, 41,106 (Oct. 19, 1988). This FFDCA risk-benefit standard *also* applies to pesticide residues which unavoidably "flow through" from crops into processed foods, provided that they do not

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[4] Since 1970 EPA has been responsible for administering FFDCA as it relates to establishing tolerances for pesticide residues. *See* 21 U.S.C. § 346a; Reorg. Plan No. 3 of 1970, §§ 2(a)(4), 2(a)(8)(i), 40 C.F.R. pt. 1 (1970), *reprinted in* 5 U.S.C. app. at 1343, 1344 (1988) (transfer of functions). The Food and Drug Administration retains responsibility only for inspecting crops and processed food products to ensure that any pesticide residues present are within the tolerance limits established by EPA.

[5] The only exception is for pesticides "generally recognized . . . as safe for use." 21 U.S.C. § 346a(a).

exceed § 408 tolerance levels. FFDCA § 402(a)(2)(C), 21 U.S.C. § 342(a)(2)(C).

Unlike § 408, which was enacted in 1954 and is specifically directed to pesticides, § 409 ("Food additives"), 21 U.S.C. § 348, enacted in 1958, is not a pesticide-specific tolerance provision. Under § 409, a "food additive," broadly defined in 21 U.S.C. § 321(s), is deemed to be unsafe, and hence, food containing the additive is regarded as adulterated and subject to seizure, unless there is a food additive regulation (i.e., § 409 tolerance) "prescribing the conditions under which such additive may be safely used." 21 U.S.C. § 348(a)(2).[6] Because of the § 402(a)(2)(C) "flow-through" provision, § 409 tolerance requirements apply only to pesticides whose residues "concentrate" in processed foods beyond § 408 tolerance levels.[7]

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[6] A "food additive" is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." 21 U.S.C. § 321(s). EPA has interpreted this definition for purposes of § 409 tolerance requirements as encompassing certain pesticide residues in processed foods. *See* 57 Fed. Reg. 20,481, 20,482-83 (May 13, 1992). In contrast, the statutory definition expressly excludes "a pesticide chemical in or on a raw agricultural commodity; or . . . a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity." 21 U.S.C. § 321(s).

[7] In absolute terms the amount of pesticide residue in a processed food is no greater than in or on the crop from which the food was processed. "Concentration" of a pesticide residue (i.e., a relative increase in the volume of the residue in comparison to the volume of the food) results from processing of the food itself. Thus, the same pesticide residues which are within § 408 tolerance limits, and hence legal, on a raw food (e.g., apples)

The language of the food additive Delaney clause, the thirty-five-year-old proviso in § 409(c)(3)(A) at the heart of this case, is totally inconsistent with the risk-benefit standard underlying FIFRA and FFDCA §§ 408 and 402(a)(2)(C). It states "[t]hat no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." 21 U.S.C. § 348(c)(3)(A). Read literally, this zero-risk language bars EPA from establishing § 409 tolerances for pesticide residues which pose even a trivial risk of cancer to consumers. For example, EPA may determine, on the basis of state-of-the-art studies, that a pesticide shows some evidence of carcinogenicity in laboratory animals, but poses no more than a negligible human dietary risk of cancer. That pesticide would be eligible for registration under FIFRA's risk-benefit standard, and also would be eligible to receive tolerances for use on food crops under the risk-benefit standard of FFDCA § 408. Under a rigid construction of the Delaney clause, however, the same pesticide would be ineligible for § 409 tolerances.

EPA's policy is "to refuse FIFRA registration and section 408 tolerances for those food uses of a pesticide that require a section 409 food additive regulation but run afoul of a strict reading of the Delaney Clause." App. B at 100a; *see* 40 C.F.R. § 152.112(g) (1992). As a result, the Delaney clause can effectively

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would render a food processed from that raw food (e.g., applesauce) adulterated if the residues "concentrate" beyond § 408 limits and no § 409 tolerance has been set.

block the use of agricultural pesticides which are vital to food production and pose only a trivial risk of cancer to consumers, but which require § 409 tolerances. Paradoxically, agricultural pesticides whose residues in processed foods do not exceed § 408 tolerance limits, and hence do not require § 409 tolerances, may be used if they satisfy the risk-benefit standards of FIFRA and FFDCA § 408, even if they pose higher-than-negligible carcinogenic risks to consumers. *See* App. B at 19a-21a (discussing the "Delaney paradox").[8]

In October 1988 EPA announced a *de minimis* exception to the § 409 Delaney clause "where the human dietary risk from residues of the pesticide is at most negligible." 53 Fed. Reg. 41,104; *see also* App. B; 57 Fed. Reg. at 20,482.[9] EPA has explained that this *de minimis* exception is necessary to regulate negligible-risk pesticides in a rational and consistent manner under FIFRA and FFDCA.

> [T]he Delaney Clause does not simply introduce an incongruity into the regulation of pesticides, it *actively interferes with the pri-*

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[8] A higher-than-negligible risk is not necessarily a significant risk. *See* App. B at 32a-45a. If a pesticide's residues in a processed food product did pose a significant risk to consumers, that presumably would tip the risk-benefit balance toward denial or cancellation of the pesticide's FIFRA registration.

[9] EPA generally regards a probability of 1 additional cancer case for every 1 million persons every 70 years as an upperbound negligible risk. *See* App. B at 33a. A negligible or trivial risk is "virtually a zero risk—too small to be of public health significance." Luise Light, Institute for Science in Society, *Unraveling Delaney's Paradox: Challenges for the 102nd Congress* 10 (1991).

> *mary framework for pesticide regulation as established by FIFRA and FFDCA section 408.* . . . [T]he Delaney Clause *directly subverts the risk/benefit balancing* that Congress so often has stated is crucial to the regulation of pesticides.
>
> Interpreting the Delaney Clause as containing a *de minimis* exception helps to reduce the conflict in the FFDCA and between the FFDCA and FIFRA. At least as to pesticides which pose a trivial cancer risk, use of a *de minimis* exception will result in *consistent treatment* of these pesticides under FFDCA, section 408, and section 409. Thus, a *de minimis* exception *harmonizes* to a degree Congress' overall legislative design for the regulation of pesticides.

App. B at 101a (emphasis added). The *de minimis* exception enables EPA to take full advantage of modern risk assessment, rather than ignore it as does the Delaney clause. Indeed, the Delaney clause was enacted before it was possible to distinguish between significant and insignificant carcinogenic risks. *See* App. B at 101a-104a. Because the *de minimis* exception only applies to negligible risks, neither the *de minimis* exception, nor this case, involve pesticides which pose a significant risk of cancer to consumers.

B. Proceedings Below

The court of appeals reviewed (App. A), pursuant to 21 U.S.C. § 348(g)(1), a Final Order issued by EPA on February 25, 1991 (App. B). The Final Order, on the basis of the *de minimis* exception, refused to revoke certain § 409 tolerances which had been

granted for four specific pesticides (trifluralin, benomyl, phosmet, and mancozeb) that were identified in EPA's October 1988 *Federal Register* notice as having "evidence of carcinogenicity" in laboratory animals. *See* 53 Fed. Reg. at 41,119. The administrative process which led to the Final Order was initiated on May 24, 1989 when an anti-pesticide coalition comprised of the then Attorney General of California,[10] Public Citizen, the AFL-CIO, the Natural Resources Defense Council, and the individuals who are the Respondents herein, filed a petition with EPA pursuant to 21 U.S.C. § 348(h) seeking revocation of those (and other) § 409 tolerances on the ground that the *de minimis* exception is unlawful. *See* 54 Fed. Reg. 27,700 (June 30, 1989).[11]

The court of appeals set aside EPA's Final Order on the ground that "the language of the Delaney clause, its history and purpose all reflect that Congress intended the EPA to prohibit all additives that are carcinogens, regardless of the degree of risk involved." App. A at 2a-3a. The court found that the

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[10] The Attorney General of California did not join the petitioners or petitioner-intervenors in the court of appeals proceeding. It should be noted that on the same day the EPA administrative petition was filed, the same petitioners and petitioner-intervenors (including the Attorney General of California) filed a district court action which also challenges EPA's implementation of the § 409 food additive Delaney clause, including the *de minimis* exception. *People v. Reilly*, No. CIV S-89-0752 WBS/GGH (E.D. Cal. filed May 24, 1989).

[11] A supplemental Final Order issued by EPA in May 1992 reconfirmed the earlier determination denying the petition to revoke certain § 409 tolerances for mancozeb. *See* 57 Fed. Reg. 20,481; App. B at 112a. The supplemental Final Order was not reviewed by the court of appeals.

Delaney clause's "language is clear and mandatory. . . . The statute provides that once the finding of carcinogenicity is made, the EPA has no discretion." *Id.* at 6a-7a. In reaching this conclusion, the court rejected or ignored EPA's and NACA's arguments that the *de minimis* principle of statutory construction (*de minimis non curat lex*: "the law cares not for trifles") governs this case; that the Delaney clause should not be interpreted in isolation; that the language of the Delaney clause conflicts with Congress' overall legislative design for pesticides, which is dominated by FIFRA and its risk-benefit standard; that the Delaney clause should not be construed as extraordinarily rigid with respect to pesticides which pose only a trivial risk of cancer to consumers of processed food; and that great deference should be afforded to EPA's *de minimis* interpretation of the Delaney clause, since for more than two decades EPA has been the sole federal agency responsible for evaluating the safety of pesticides and implementing the substantive requirements of the pesticide regulatory scheme.

Following denial of EPA's petition for rehearing, the court on October 8, 1992 granted separate motions filed by Petitioner and EPA pursuant to Fed. R. Civ. P. 41(b) for a stay of the mandate pending application to this Court for a writ of certiorari.

REASONS FOR GRANTING THE WRIT

I. THE NINTH CIRCUIT'S DECISION HAS FAR-REACHING CONSEQUENCES FOR THE PUBLIC, AGRICULTURE, THE FOOD AND PESTICIDE INDUSTRIES, AND EPA'S PESTICIDE REGULATORY PROGRAM

If the Ninth Circuit's decision is allowed to stand, it will derail Congress' carefully balanced statutory

machinery for regulating the use of agricultural pesticides. EPA has indicated that dozens of widely-used agricultural pesticides may have to be banned. That would significantly disrupt production of commodities such as wheat, corn, soybeans, and cotton, and scores of fruit and vegetable crops. In turn, that would curtail the nation's supply of processed foods. Government agencies even may seize food products from processing plants and supermarket shelves on the theory that they are adulterated by unlawful pesticide residues. The public undoubtedly would lose confidence in the safety of the food supply, and pay higher prices for whatever processed food products remain available. Moreover, pesticide manufacturers would have no incentive for investing tens of millions of dollars in development of valuable, negligible-risk pesticides which would be barred from use as a result of the Ninth Circuit's Delaney clause decision.

EPA Administrator William K. Reilly, in remarks to the pesticide industry regarding the potential impact of the Ninth Circuit's decision, explained that

> [*t*]*he consequences of this court decision are potentially far-reaching and profound.*
>
> . . . . As a result of this decision, for example, low dietary risk pesticides could be removed from the market, *only to be replaced by pesticides posing potentially more harmful effects*. I'm no less concerned that this decision will divert EPA's energy and resources from more worthwhile actions—actions that are crucial to EPA, to farmers, and to NACA, like the registration of new and improved chemicals and re-registration of older ones.

William K. Reilly, Remarks at the National Agricultural Chemicals Association Annual Meeting 3 (Sept. 28, 1992) (emphasis added) (transcript available from EPA Office of Administrator).

Linda J. Fisher, EPA's Assistant Administrator for Prevention, Pesticides and Toxic Substances, testified before Congress that

> if the Ninth Circuit's decision stands at the end of the day, *I foresee far-reaching and dramatic impacts on pesticide use in this country*. While I wish that I could say that these changes will contribute measurably to the safety of the food supply, it is not at all clear that that would be true.

Before the Subcomm. on Environment, Energy, and Natural Resources of the House Comm. on Government Operations 22 (July 23, 1992) (statement of Linda J. Fisher, Assistant Administrator for Prevention, Pesticides and Toxic Substances, EPA) (emphasis added). She testified that "[t]he Ninth Circuit decision applies only to the four pesticides at issue in the litigation, but *the court's ruling logically would extend to numerous other pesticides* that have or need section 409 food additive tolerances." *Id.* at 19 (emphasis added). Ms. Fisher indicated that "[a]t this point EPA has identified roughly thirty (30) pesticides" which may have "violative residues" under the court's ruling. *Id.* "These pesticides, however, are *only a portion of the total universe that could be affected*, since there are *at least three dozen more pesticides* with registered food uses, and *some* evidence of carcinogenic effects." *Id.* (emphasis added). Moreover, Ms. Fisher testified that "EPA, in consultation with the Food and Drug

Administration, must carefully consider whether following the revocation of tolerances the government should take *enforcement actions against food in supermarkets and processing plants that contain residues that were previously legal.*" *Id.* at 21 (emphasis added).

Respondents have been no less emphatic regarding the substantial impact of the Ninth Circuit's ruling. Their lead counsel was quoted in many front page newspaper stories around the country after the court of appeals issued its decision. He proclaimed that "the ruling [is] 'the *Brown versus Board of Education* of the pesticide world,' establishing legal principles of pesticide regulation much as the landmark civil rights ruling did for desegregation." Michael Weisskopf, *Court Curbs Carcinogenic Pesticide Use*, Wash. Post, July 9, 1992, at A1. He also declared that "[t]his decision will provide a powerful catalyst to force American agriculture to get off the pesticide treadmill." Keith Schneider, *Court Expands Pesticide Ban to Cover Many Used in Food*, N.Y. Times, July 9, 1992, at A1, A16. He (like EPA) indicated that "[d]ozens" of agricultural pesticides "could be banned under the ruling." Maura Dolan, *Court Bans 4 Chemicals from Processed Foods*, L.A. Times, July 8, 1992, at A1.

In light of these sweeping ramifications, and the Ninth Circuit's erroneous reading of the Delaney clause, Supreme Court review of the *de minimis* issue is essential. A final determination by this Court not only is critically important to consumers, agriculture, and industry, but also to EPA, which is responsible for regulating public health risks in a rational, consistent, and scientifically sound manner.

II. THE NINTH CIRCUIT'S DECISION CONFLICTS WITH THE *DE MINIMIS* DOCTRINE LONG RECOGNIZED BY THIS COURT

" '[S]afe' is not the equivalent of 'risk-free.' " *Industrial Union Department v. American Petroleum Institute*, 448 U.S. 607, 642 (1980) (setting aside workplace benzene standard which OSHA promulgated after it concluded that there is no absolutely safe level for human exposure to carcinogens). "There are many activities that we engage in every day . . . that entail some risk of accident or material health impairment; nevertheless, few people would consider these activities 'unsafe.' " *Id.* In other words, "[s]ome risks are plainly acceptable." *Id.* at 655. For this reason, federal regulatory statutes confer upon agencies "[i]nherent . . . authority to refrain from regulation of insignificant or *de minimis* risks." *Id.* at 663-64 (Burger, J., concurring) (citing *Alabama Power Co. v. Costle*, 636 F.2d 323, 360-61 (D.C. Cir. 1980)).

The Ninth Circuit held that EPA lacks authority to exempt *de minimis* pesticide risks because the Delaney clause says what it says:

> The language is clear and mandatory. The Delaney clause provides that no additive shall be deemed safe if it induces cancer. . . . The statute provides that once the finding of carcinogenicity is made, the EPA has no discretion.

App. A at 6a-7a. This conclusion, reflecting the Ninth Circuit's rigid adherence to the literal language of the Delaney clause, squarely conflicts with the *de minimis* principle of statutory construction repeatedly recognized by this Court.

For example, last Term in *Wisconsin Department of Revenue v. William Wrigley, Jr., Co.*, 112 S. Ct. 2447 (1992), the Court considered the issue of whether there is a *de minimis* exception to an immunity provision in a state franchise tax statute. The immunity provision exempts from taxation out-of-state companies whose only in-state business activity is solicitation of sales orders. The question was whether the immunity provision encompassed certain additional, "*de minimis*" in-state business activities. The state tax agency asserted "that the plain language of the statute bars this recognition of a *de minimis* exception." *Id.* at 2457. The Court rejected the state's "plain language" argument because it

> ignores the fact that the venerable maxim *de minimis non curat lex* ("the law cares not for trifles") is part of the established background of legal principles *against which all enactments are adopted*, and which all enactments (absent contrary indication) are deemed to accept. See, *e.g.*, *Republic of Argentina v. Weltover, Inc.*, ___ U.S. ___, ___, 112 S.Ct. 2160, 2168, ___ L.Ed.2d ___ (1992); *Hudson v. McMillian*, 503 U.S. ___, ___, 112 S.Ct. 995, 1000, 117 L.Ed.2d 156 (1992); *Ingraham v. Wright*, 430 U.S. 651, 674, 97 S.Ct. 1401, 1414, 51 L.Ed.2d 711 (1977); *Abbott Laboratories v. Portland Retail Druggists Assn., Inc.*, 425 U.S. 1, 18, 96 S.Ct. 1305, 1316, 47 L.Ed.2d 537 (1976); *Industrial Assn. of San Francisco v. United States*, 268 U.S. 64, 84, 45 S.Ct. 403, 408, 69 L.Ed. 849 (1925).

Id. at 2457-58. The Ninth Circuit's "plain language" interpretation of the Delaney clause ignores this *de minimis* principle.

Noting that an out-of-state company would be liable for hundreds of thousands of dollars in taxes if a salesman sold a 10-cent item in-state, the Supreme Court emphasized in *Wrigley* that "[i]t would be especially unreasonable to abandon normal application of the *de minimis* principle in construing [a statute] which operates in such *stark, all-or-nothing* fashion." *Id.* at 2458 (emphasis added). It would be just as unreasonable to abandon the *de minimis* principle in the case of the food additive Delaney clause, yet that is *exactly* what the Ninth Circuit did by holding that the clause "prohibit[s] all additives that are carcinogens, regardless of the degree of risk involved." App. A at 3a. Unless this Court reviews and reverses the Ninth Circuit's holding, the Delaney clause will operate in a stark, all-or-nothing (and completely irrational) fashion: It will effectively bar use of pesticides whose residues in processed foods exceed § 408 tolerance levels but pose only a trivial risk of cancer, while allowing use of pesticides whose residues in processed foods pose higher-than-negligible risks to consumers but do not require § 409 tolerances.

The Court explained in *Wrigley* that the mere presence of restrictive language in a statutory provision does not preclude a *de minimis* exception. The Court held that the tax immunity provision at issue in *Wrigley* "places a strict limit upon the *categories* of activities that are covered . . . not upon their *substantiality*." 112 S. Ct. at 2458. Similarly, the mere presence of restrictive language in the Delaney clause (i.e., language declaring that food additives which

"induce cancer" are unsafe) does not preclude a *de minimis* exception for pesticide residues which pose essentially a zero risk of inducing cancer in consumers. The Ninth Circuit missed this critical point completely, holding instead that the Delaney clause's "language is clear and mandatory," even for trivial risks. App. A at 6a.

III. THE NINTH CIRCUIT'S DECISION CONFLICTS WITH THE D.C. CIRCUIT'S DELANEY CLAUSE *DE MINIMIS* ANALYSIS IN *PUBLIC CITIZEN v. YOUNG*

The court of appeals unjustifiably cited *Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988), as authority for rejection of EPA's *de minimis* interpretation of the food additive Delaney clause. *See* App. A at 7a. In *Public Citizen* the D.C. Circuit concluded "with some reluctance" that a *de minimis* exception cannot be read into FFDCA's *color* additive Delaney clause, 21 U.S.C. § 376(b)(5)(B) (1988), a wholly separate provision. 831 F.2d at 1109. The D.C. Circuit emphasized that "the operation of the food additive Delaney Clause raises complex issues distinct from those" raised in the color additive Delaney clause; that "[a]lthough the clauses have almost identical wording, the context is clearly different"; and that the question of whether the food additive Delaney clause contains a *de minimis* exception is not "foreordained" by the court's decision on the color additive Delaney clause. *Id.* at 1118 n.13, 1120.

The Ninth Circuit disregarded not only these caveats, but also the *de minimis* principles which the D.C. Circuit articulated and followed in the *Public Citizen* case. In particular, the Ninth Circuit utterly failed to consider whether EPA's *de minimis* excep-

tion serves as a "tool to be used in implementing the legislative design" for pesticides. *Id.* at 1113 (quoting *Alabama Power Co. v. Costle*, 636 F.2d at 360). The D.C. Circuit explained that the *de minimis* doctrine "must be interpreted with a view to 'implementing the legislative design'" because failure to employ a *de minimis* exception "may lead to regulation that not only is 'absurd or futile' in some general cost-benefit sense but also is directly contrary to the *primary* legislative goal." *Id.*

Despite the fact that FIFRA is the *principal* pesticide regulatory statute, and although its risk-benefit standard *dominates* Congress' legislative design for pesticides, *the Ninth Circuit virtually ignored FIFRA*, mentioning it only in passing. *See* App. A at 10a. This gaping omission renders the court's scant *de minimis* "analysis" wholly inadequate and patently defective.

The court failed to consider the manner in which the *de minimis* exception helps to implement Congress' legislative design for pesticides by enabling EPA to avoid, for negligible-risk pesticides, the obvious conflict between the Delaney clause and FIFRA's risk-benefit standard. *See* App. B at 98a-100a. Instead, the court purported to deal with "the overall statutory scheme governing pesticides" by briefly discussing the relationship between FFDCA §§ 409 and 402(a)(2)(C), and then focusing almost exclusively on the Delaney clause itself. App. A at 7a-8a. Having failed even to recognize the conflict between the Delaney clause and the risk-benefit standard contained in FFDCA § 408, the court erroneously concluded that § 402(a)(2)(C) (the "flow-through" provision which incorporates the § 408 risk-benefit standard) "expressly

harmonizes [the pesticide] scheme with the Delaney clause." *Id.* To the contrary, it is the *de minimis* exception which harmonizes, for pesticides which pose trivial risks, the Delaney clause with Congress' legislative design for pesticides.

In *Public Citizen* the D.C. Circuit described

> the standard for application of *de minimis* as virtually a *presumption in its favor*: "Unless Congress has been extraordinarily rigid, there is likely a basis for an implication of *de minimis* authority to provide [an] exemption where the burdens of regulation yield a gain of trivial or no value."

831 F.2d at 1113 (quoting *Alabama Power*, 636 F.2d at 360-61) (emphasis added). Because the Ninth Circuit ignored this presumption and read the Delaney clause and its legislative history in isolation, rather than in the context of the full pesticide regulatory scheme, the court erroneously concluded that Congress intended the clause to be applied with "rigidity," including with respect to pesticide residues in processed foods. App. A at 8a-9a. Yet the court acknowledged that the legislative history of § 409 "does not focus on pesticides." *Id.* at 10a.

The court did not consider the vast majority of Congress' statutory scheme for pesticides, including especially FIFRA and its legislative history, and as a result, failed to recognize that Congress could not have intended the Delaney clause to be "extraordinarily rigid" with respect to negligible-risk pesticides. Such an interpretation of the Delaney clause directly conflicts with the risk-benefit standard which overwhelmingly pervades the pesticide regulatory scheme,

and *authorizes* use of beneficial pesticides which pose merely a trivial risk of cancer.

In *Public Citizen* the D.C. Circuit found that Congress intended the legislative design for *color* additives to be "extraordinarily rigid," thereby precluding a *de minimis* interpretation of the color additive Delaney clause, because Congress "perceived color additives as lacking any great value. . . . there is evidence that Congress thought the public could get along without carcinogenic colors." 831 F.2d at 1117. Exactly the *opposite* is true for agricultural pesticides, the necessity for which Congress has repeatedly stressed. When Congress modernized FIFRA in 1972, it incorporated consideration of the "economic, social, and environmental . . . benefits" of pesticides into the statutory risk-benefit standard for registration, explaining that "[p]esticides are essential to man's food supply both as to quality and quantity." 7 U.S.C. §§ 136a(c)(5), 136(bb); S. Rep. No. 838, 92d Cong., 2d Sess. 3, *reprinted in* 1972 U.S.C.C.A.N. 3993, 3995. In 1977 Congress reaffirmed that "[a]n overriding concern of FIFRA is that pesticides should be available to meet pest control needs." S. Rep. No. 334, 95th Cong., 1st Sess. 3, 5 (1977). Similarly, when Congress accelerated FIFRA's reregistration procedures in 1988, it sought to ensure "that pesticides are approved and used in a manner that meets contemporary health and safety standards [and] that affordable and effective products are available to pesticide users." S. Rep. No. 346, 100th Cong., 2d Sess. 6 (1988).

By misplacing reliance on *Public Citizen*'s color additive findings and disregarding the *de minimis* principles which govern this case, the Ninth Circuit has

held unlawful EPA's *de minimis* interpretation without even considering the critically important role that the *de minimis* exception fulfills in avoiding the conflict between the zero-risk language of the food additive Delaney clause and the risk-benefit standard mandated by FIFRA and by FFDCA's pesticide-specific tolerance provisions. EPA has explained that "[t]he *de minimis* exception simply recognizes that the Delaney Clause should not be a bar to the use of a pesticide that satisfies the statutory standard of FIFRA [and FFDCA § 408] for a carcinogenic pesticide which presents a trivial risk." 55 Fed. Reg. 17,560, 17,565-66 (Apr. 25, 1990). This is a point which the court of appeals ignored entirely.

IV. THE NINTH CIRCUIT'S DECISION FAILS TO AFFORD DEFERENCE TO EPA'S INTERPRETATION OF THE STATUTORY SCHEME WHICH IT ADMINISTERS

Since its creation in 1970, EPA has been the *sole* agency responsible for administering the substantive provisions of the federal statutory scheme for pesticides, including the FFDCA § 409 Delaney clause as it pertains to pesticide residues in processed foods.[12] The Final Order which the court of appeals reviewed contains an exhaustive discussion of the basis for EPA's *de minimis* interpretation. *See* App. B at 17a-108a; *see also* 53 Fed. Reg. at 41,104-10; 55 Fed. Reg. at 17,560-74; 57 Fed. Reg. at 20,482-85. Nevertheless, the Ninth Circuit gave no deference to EPA, and erroneously characterized EPA's rationale for the

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[12] As noted, FDA merely inspects crops and processed foods to enforce the tolerance requirements which EPA establishes pursuant to FFDCA §§ 408 and 409.

de minimis exception as an attempt to "[r]evis[e] the existing statutory scheme." App. A at 11a.

The court missed the whole point of the *de minimis* doctrine: "The ability . . . to exempt *de minimis* situations from a statutory command is not an ability to depart from the statute, but rather a tool to be used in implementing the legislative design." *Alabama Power Co. v. Costle*, 636 F.2d at 360. Thus, "[c]ourts (and agencies) are not . . . helpless slaves to literalism." *Public Citizen v. Young*, 831 F.2d at 1112. "Where the literal reading of a statutory term would 'compel an odd result,' " it is appropriate to "search for other evidence of congressional intent." *Public Citizen v. United States Department of Justice*, 491 U.S. 440, 454 (1989) (quoting *Green v. Bock Laundry Machine Co.*, 490 U.S. 504, 509 (1989)). "Looking beyond the naked text for guidance is perfectly proper . . . where [the result] seems inconsistent with Congress' intention, since the plain-meaning rule is 'rather an axiom of experience than a rule of law, and does not preclude consideration of persuasive evidence if it exists.' " 491 U.S. at 455 (quoting *Boston Sand & Gravel Co. v. United States*, 278 U.S. 41, 48 (1928)).

As the agency responsible for implementing Congress' legislative design for pesticides, EPA has adopted a *de minimis* interpretation of the food additive Delaney clause to harmonize it with FIFRA and the pesticide-specific tolerance provisions of FFDCA. The language of a statute should not be construed "to mandate a result in one clause, only to preclude that result in the next clause." *Cook Inlet Native Ass'n v. Bowen*, 810 F.2d 1471, 1474 (9th Cir. 1987); *see also Chemical Manufacturers Ass'n v. Natural Re-*

sources Defense Council, Inc., 470 U.S. 116, 126 (1985). Instead, "[t]he words of a statute should be harmonized internally and with each other to the extent possible." *Cook Inlet Native Ass'n v. Bowen*, 810 F.2d at 1474.

The *de minimis* interpretation is well within EPA's authority, and the Ninth Circuit should have given deference to it. This Court has "long recognized that considerable weight should be accorded to an [agency's] construction of a statutory scheme it is entrusted to administer." *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984).

As the Ninth Circuit recognized in a previous case involving FIFRA, it

> is often the case where Congress drafts complex statutes [that] the various provisions do not fit with surgical precision. While the statute's meaning may be clear as to most of the situations it covers, cases may arise where two provisions in the same statute, or in different statutes, apparently conflict.

Love v. Thomas, 858 F.2d 1347, 1354 (9th Cir. 1988), *cert. denied*, 490 U.S. 1035 (1989). That is the situation here. While the meaning of the Delaney clause may be clear with respect to non-pesticide food additives regulated exclusively under FFDCA, its zero-risk language conflicts with EPA's mandate under FIFRA and FFDCA § 408 to regulate pesticides based on balancing benefits against the degree of risk that they pose. For this reason, it is appropriate for EPA to construe these statutes "so that they are consistent with each other" with respect to pesticides that pose a trivial risk of cancer, "as by this means congres-

sional intent can be given its fullest expression." *Get Oil Out! Inc. v. Exxon Corp.*, 586 F.2d 726, 729 (9th Cir. 1978).

Rather than affording deference to EPA's interpretation of the Delaney clause insofar as it pertains to pesticides whose safety Congress entrusted EPA alone to evaluate, the court of appeals gave "great weight" to a 1958 "contemporaneous" interpretation by the now-defunct Department of Health, Education, and Welfare ("HEW") (of which FDA was a part). App. A at 9a. HEW's supposed administrative interpretation, however, did not focus on pesticides, and was in the form of a letter from the Secretary of HEW to a congressional committee endorsing the proposed FFDCA food additive amendment. *See* 104 Cong. Rec. 17,412, 17,415 (1958), *reprinted in* XIV HEW, *A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments* 869 (1979).[13] Moreover, FDA not only has been out of the pesticide tolerance-setting business for more than twenty-two years, it *never* was responsible for administering FIFRA.[14] Therefore, unlike EPA, which

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[13] According to the court, HEW "interpreted the clause as removing all agency discretion regarding carcinogens." App. A at 9a. What the Secretary of HEW actually said, however, was that "[t]his Department is in complete accord with the intent . . . that no substance should be sanctioned for uses in food that might produce cancer *in man*." 104 Cong. Rec. at 17,415 (emphasis added). Thus, the Secretary did not offer the extraordinarily rigid interpretation of the Delaney clause which the court suggests. Furthermore, the Secretary admonished the Committee "to use language that would provide the intended safeguards without creating unintended and unnecessary complications." *Id.*

[14] Prior to EPA's creation in 1970, the United States De-

has had decades of experience in implementing the *entire* pesticide regulatory scheme, and has unique expertise on how FIFRA and the Delaney clause interact, FDA was in no position to know in 1958, before the food additive Delaney clause even was enacted, that it would conflict with FIFRA and Congress' legislative design for pesticides.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

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partment of Agriculture was responsible for administering FIFRA. *See* 35 Fed. Reg. 15,623 (1970) (transferring to EPA pesticide regulatory functions of USDA under FIFRA and FDA under FFDCA pursuant to Reorg. Plan No. 3 of 1970, 40 C.F.R. pt. 1 (1970), *reprinted in* 5 U.S.C. app. at 1343 (1988)).